



MICHAEL ANDERSON

Quality Assurance Specialist

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SUMMARY

Detail-oriented Biomedical Compliance Specialist with over 7 years of experience in the pharmaceutical industry. Proven track record in ensuring compliance with regulatory standards and guidelines, including FDA and EMA regulations. Skilled in developing and implementing quality management systems, conducting audits, and training staff on compliance procedures. Adept at analyzing complex regulatory documents and collaborating with cross-functional teams to facilitate successful audits and inspections.

WORK EXPERIENCE

Quality Assurance Specialist PharmaTech Inc.

Jan 2023 - Present

- Conducted internal audits to assess compliance with regulatory standards.
- Developed and implemented corrective action plans for non-compliance issues.
- Collaborated with R&D teams to ensure product compliance from development to market.
- Trained staff on quality assurance protocols and compliance regulations.
- Reviewed and approved batch records and deviation reports.
- Participated in regulatory inspections, leading to zero findings in the last three audits.

Regulatory Affairs Associate BioHealth Corp.

Jan 2020 - Dec 2022

- Prepared and submitted regulatory documents for product approvals.
 - Maintained up-to-date knowledge of changes in biomedical regulations.
 - Assisted in the development of product labeling and marketing strategies.
 - Worked closely with manufacturing to ensure compliance with GMP standards.
 - Conducted training sessions on regulatory requirements for new hires.
 - Contributed to successful product launches by ensuring timely regulatory submissions.
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EDUCATION

Bachelor of Science in Biomedical Engineering, University of California, 2013

Sep 2019 - Oct 2020

ADDITIONAL INFORMATION

- **Technical Skills:** Regulatory compliance, Quality management systems, Auditing, Training, Documentation, Risk assessment
- **Awards/Activities:** Improved compliance audit scores by 30% over two years.
- **Awards/Activities:** Developed a training manual that reduced onboarding time by 25%.
- **Awards/Activities:** Recognized as 'Employee of the Year' for outstanding contributions to compliance protocols.
- **Languages:** English, Spanish, French